IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond **DIVISION**

LIFENET HEALTH, A Virginia Corporation Plaintiff, v. LIFECELL CORPORATION, A Delaware Corporation Defendant.	Civil Action No. 3:17cv168 **JURY TRIAL DEMANDED**

COMPLAINT

LifeNet Health, by and through its undersigned counsel, states as follows for its complaint against the defendant, LifeCell Corporation ("LifeCell"):

I. THE PARTIES

A. LifeNet Health

1. LifeNet Health is a nonprofit corporation organized under 26 U.S.C. § 501(c)(3) and existing under the laws of the Commonwealth of Virginia and having a principal place of business in this judicial district at 1864 Concert Drive, Virginia Beach, Virginia 23453.

2. LifeNet Health's mission statement is "Saving Lives, Restoring Health and Giving Hope." Founded in 1982 as the Eastern Virginia Tissue Bank, LifeNet Health is one of the world's most trusted providers of transplant solutions, from organ and tissue procurement to innovative bio-implant technologies and cellular therapies.

3. Each year, LifeNet Health facilitates the transplantation of over 400 organs in the United States and distributes over 500,000 allograft bio-implants to meet the needs of hospitals

and patients in the United States. An allograft is human donor tissue, such as skin, bone, tendon, and cardiovascular tissue, intended for transplantation in a human recipient.

4. LifeNet Health is also extensively involved in promoting and facilitating tissue-donation and bio-implant tissues. For example, LifeNet Health's Tissue Services Division is dedicated to training, educating, and maintaining relationships with more than 50 partners to promote tissue donation in their respective communities.

5. LifeNet Health also established its Plastic & Reconstructive Surgical Specialties franchise to ensure the processing and delivery of skin/dermal allograft bio-implants for U.S. trauma and burn centers.

6. In addition, LifeNet Health's Bio-Implants Division has pioneered technologies related to all aspects of the allograft bio-implant production process, including disinfection, decellularization (the removal of cellular elements from an allograft bio-implant), preservation, and sterilization.

7. LifeNet Health is also a member of several organizations related to tissue donation. For example, LifeNet Health is an accredited member of the American Association of Tissue Banks, and also a member organization of Donate Life America, a not-for-profit alliance of national organizations across the United States committed to increasing organ, eye, and tissue donation.

8. The patent asserted by LifeNet Health in this Complaint and a patent application that is due to issue on March 7, 2017 are a result of LifeNet Health's extensive research and development in the field of tissue and bio-implant technology.

B. LifeCell Corporation

9. Upon information and belief, LifeCell is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 95 Corporate Drive, Bridgewater, New Jersey 08807.

10. LifeCell is in the business of manufacturing, selling, and offering for sale various medical products including skin/dermal products under the brand names Strattice Reconstructive Tissue Matrix, Strattice Reconstructive Tissue Matrix Extra Thick, Strattice Reconstructive Tissue Matrix Laparoscopic, Strattice Reconstructive Tissue Matrix Perforated, Conexa Reconstructive Tissue Matrix, Artia Reconstructive Tissue Matrix, AlloDerm Reconstructive Tissue Matrix Ready to Use, and AlloDerm Select Regenerative Tissue Matrix Ready to Use.

11. Upon information and belief, Strattice Reconstructive Tissue Matrix, Strattice Reconstructive Tissue Matrix Extra Thick, Strattice Reconstructive Tissue Matrix Laparoscopic, Strattice Reconstructive Tissue Matrix Perforated, Conexa Reconstructive Tissue Matrix, and Artia Reconstructive Tissue Matrix are porcine (pig) skin xenografts (the "Infringing Xenograft Products"). AlloDerm Reconstructive Tissue Matrix Ready to Use, and AlloDerm Select Regenerative Tissue Matrix Ready to Use are human dermal allografts (the "Infringing Allograft Products"). Collectively, the Infringing Xenograft Products and the Infringing Allograft Products are referred to herein as the "Infringing Products."

II. JURISDICTION AND VENUE

12. This action is a claim for patent infringement arising under the Patent Laws of the Unites States, 35 U.S.C. § 271 *et seq*.

13. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1332, and 1338(a).

14. This Court has personal jurisdiction over LifeCell at least because LifeCell has substantial, continuing, and on-going contacts within the Commonwealth of Virginia and this judicial district, and LifeCell has sold and continues to sell the products at issue in this case in this Commonwealth and judicial district.

15. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and 1400(b) in that acts of patent infringement have occurred and are occurring within this judicial district.

III. FACTS

A. U.S. Patent No. 9,579,420

16. On February 8, 2010, U.S. Patent Application No. 12/701,634 (the "'634 application") was filed on behalf of inventors Lloyd Wolfinbarger, Jr., Robert K. O'Leary, and Billy G. Anderson (deceased) by plaintiff LifeNet Health.

17. On February 28, 2017, the '634 application was issued by the U.S. Patent and Trademark Office ("USPTO") as U.S. Patent No. 9,579,420 (the "'420 patent").

18. The '420 patent claims priority through a series of applications to U.S. Patent Application No. 09/107,459, filed June 20, 1998, which later issued as U.S. Patent No. 6,293,970 (the "'970 patent").

19. LifeNet Health is the assignee of all right, title, and interest in and to the '420 patent and possesses all rights of recovery under the '420 patent. The '420 patent is one of several issued patents in the '970 patent family.

20. As stated in the Abstract of the '420 patent, the invention is directed to, *inter alia*, "plasticized dehydrated or freeze-dried bone and/or soft tissue product[s] that do[] not require special conditions of storage," and methods for producing the same.

21. As is also stated in the Abstract of the '420 patent, "[t]he invention replaces water in the molecular structure of the bone or soft tissue matrix with one or more plasticizers allowing for dehydration of the tissue, yet not resulting in an increase in brittleness of the plasticized product, and resulting in compressive and/or tensile properties similar to those of normal hydrated bone. Replacement of the chemical plasticizers by water prior to implantation is not required and thus, the dehydrated bone or soft tissue plasticized product can be placed directly into an implant site without significant preparation in the operating room." *Id*.

22. In 2007, LifeNet Health introduced Preservon® technology, its proprietary bio-implant tissue-preservation technology based on the '970 patent family. It is an ambient-temperature (*i.e.*, room-temperature) preservation method that simplifies the tissue-preparation and product-distribution processes and storage, saves valuable time in the operating room, and allows tissue to retain its physical and biomechanical properties.

B. Prior Litigation Regarding the '970 Patent Family

23. In September 2013, LifeNet Health filed suit in this Court asserting infringement of U.S. Patent No. 6,569,200 (the "'200 patent") against LifeCell. *See* D.I. 1, Civil Action No. 2:13-cv-00486, September 6, 2013 (E.D. Va.) (the "'200 patent litigation"). The '200 patent's disclosure is substantively identical to that in the '420 patent.

24. After a ten-day jury trial, the '200 patent was held to be valid and infringed, and damages were awarded to LifeNet Health. *See* '200 patent litigation, D.I. 369. The verdict in LifeNet Health's favor was upheld on appeal. *See LifeNet Health v. LifeCell Corp.*, 837 F.3d 1316 (Fed. Cir. 2016).

25. In September 2015, LifeCell filed a declaratory judgment action asserting non-infringement of U.S. Patent No. 9,125,971 (the "'971 patent"). *See* D.I. 1, Civil Action No.

2:15-cv-06701, September 8, 2015 (D.N.J.) (the "'971 patent suit"). The '971 patent is also in the '970 patent family. After transfer to this Court, the '971 patent suit was dismissed.

26. On the same day the '971 patent suit was filed, LifeCell filed a petition for *inter partes* review of the '971 patent. That proceeding ended when LifeNet Health requested an adverse judgment.

C. LifeCell's Infringing Products

27. Upon information and belief, Defendant has been using, manufacturing, selling, and offering for sale a tissue product under the brand name Strattice Reconstructive Tissue Matrix ("Strattice").

28. Defendant makes the following claims about Strattice:

- "Strattice™ Reconstructive Tissue Matrix is an acellular reconstructive tissue matrix . . . derived from porcine dermis, which undergoes non-damaging proprietary processing that removes cells . . . ." Strattice Product Page (attached as Exhibit A) at 1;
- Strattice "requires no rehydration or orientation and can be stored at room temperature." *Id.*; and
- Strattice is a "a surgical mesh that is derived from porcine skin and is processed and preserved in a phosphate buffered aqueous solution containing matrix stabilizers," and that Strattice "should be stored in a clean, dry location at room temperature." Strattice Implantation Instructions (attached as Exhibit B) at 1, 2.

29. Strattice was found to infringe claims 1-4, 7, 8, and 10 of the '200 patent. *See* '200 patent litigation, D.I. 369 at 1.

30. Upon information and belief, Strattice is a plasticized soft tissue graft as set forth in at least claims 1-4, 17, 18, 20, and 36 of the '420 patent.

31. Upon information and belief, Strattice is a plasticized soft tissue graft produced by the methods set forth in at least claims 8, 23, 24, 26, 29, and 32 of the '420 patent.

32. Upon information and belief, Defendant has been using, manufacturing, selling, and offering for sale a tissue product under the brand name Strattice Reconstructive Tissue Matrix Extra Thick ("Strattice Extra Thick").

33. Defendant makes the following claims about Strattice Extra Thick:

- "STRATTICE™ Reconstructive Tissue Matrix (RTM) Extra Thick is the newest member of the robust LifeCell abdominal wall portfolio . . . and the strongest STRATTICE™ Tissue Matrix yet." http://www.acelity.com/StratticeExtraThick (visited February 23, 2017) (attached as Exhibit C) at 15;
- Strattice Extra Thick "has the same biologic response as STRATTICE™ RTM." *Id.*;
- "The LifeCell process minimizes damage to the tissue matrix in order to support tissue regeneration and retain the tissue's native properties out of the package." *Id.* at 17; and
- Strattice Extra Thick "is a surgical mesh that is derived from porcine skin." *Id.* at 19.

34. Upon information and belief, Strattice Extra Thick is a plasticized soft tissue graft as set forth in at least claims 1-4, 17, 18, 20, and 36 of the '420 patent.

35. Upon information and belief, Strattice Extra Thick is a plasticized soft tissue graft produced by the methods set forth in at least claims 8, 23, 24, 26, 29, and 32 of the '420 patent.

36. Upon information and belief, Defendant has been using, manufacturing, selling, and offering for sale a tissue product under the brand name Strattice Reconstructive Tissue Matrix Laparoscopic ("Strattice Laparoscopic").

37. Defendant makes the following claims about Strattice Laparoscopic:

- "Because ease of use, strength, and performance all matter in a laparoscopic biological mesh, we developed STRATTICE™ Tissue Matrix Laparoscopic (TML) for laparoscopic ventral hernia repair. Prepared with the same proprietary processing as STRATTICE™ Tissue Matrix, STRATTICE™ TML provides the same regenerative benefits with a thickness more suitable for laparoscopic handling." http://www.acelity.com/products/strattice-tissue-matrix-laparoscopic (visited February 24, 2017) (attached as Exhibit D) at 10;

- "The LifeCell proprietary tissue process minimizes damage to the tissue matrix in order to support tissue regeneration and retain the tissue's native properties out of the package." *Id.* at 11; and

- "This surgical mesh is derived from a porcine source." *Id.* at 12.

38. Upon information and belief, Strattice Laparoscopic is a plasticized soft tissue graft as set forth in at least claims 1-4, 17, 18, 20, and 36 of the '420 patent.

39. Upon information and belief, Strattice Laparoscopic is a plasticized soft tissue graft produced by the methods set forth in at least claims 8, 23, 24, 26, 29, and 32 of the '420 patent.

40. Upon information and belief, Defendant has been using, manufacturing, selling, and offering for sale a tissue product under the brand name Strattice Reconstructive Tissue Matrix Perforated ("Strattice Perforated").

41. Defendant makes the following claims about Strattice Perforated:

- "New STRATTICE™ Reconstructive Tissue Matrix (RTM) Perforated delivers the regenerative performance you have come to expect from STRATTICE™ Tissue Matrix, and is now perforated to help meet your surgical needs." http://www.acelity.com/products/strattice-perforated (visited February 24, 2017) (attached as Exhibit E) at 14;

- "STRATTICE™ RTM Perforated is manufactured using the same proprietary LifeCell tissue processing technology as STRATTICE™ Tissue Matrix. This process retains the integrity of the matrix to support tissue regeneration, as shown in an animal study." *Id.* at 15; and

- "This device is derived from a porcine source." *Id.* at 18.

42. Upon information and belief, Strattice Perforated is a plasticized soft tissue graft as set forth in at least claims 1-4, 17, 18, 20, and 36 of the '420 patent.

43. Upon information and belief, Strattice Perforated is a plasticized soft tissue graft produced by the methods set forth in at least claims 8, 23, 24, 26, 29, and 32 of the '420 patent.

44. Upon information and belief, Defendant has been using, manufacturing, selling, and offering for sale a tissue product under the brand name Conexa Reconstructive Tissue Matrix ("Conexa").

45. Upon information and belief, Defendant manufactures Conexa for Tornier, Inc. ("Tornier"). *See* Exhibit F at 8 ("Manufactured by: LifeCell Corp. . . . .").

46. Tornier makes the following claims about Conexa:

- "Sterile. Ready to use. Supports regeneration. Conexa provides a complex three-dimensional architecture with preserved essential matrix components that support regeneration. With no extended time needed for rehydration, Conexa offers a ready-to-use biological solution for soft tissue repair." http://www.tornier-us.com/biologics/bio004/ (visited February 24, 2017) (attached as Exhibit G at 1;
- "Porcine dermis." *Id.*; and
- "Conexa is stored at room temperature, -8°C to 30°C (18°F to 86°F). Some competitors' matrices must be rehydrated which can take from 10-60 minutes, taking up more OR time and increasing the cost of each procedure." *Id.* at 2.

47. Conexa was found to infringe claims 1-4, 7, 8, and 10 of the '200 patent. See '200 patent litigation, D.I. 369 at 3.

48. Upon information and belief, Conexa is a plasticized soft tissue graft as set forth in at least claims 1-4, 17, 18, 20, and 36 of the '420 patent.

49. Upon information and belief, Conexa is a plasticized soft tissue graft produced by the methods set forth in at least claims 8, 23, 24, 26, 29, and 32 of the '420 patent.

50. Upon information and belief, Defendant has been using, manufacturing, selling, and offering for sale a tissue product under the brand name Artia Reconstructive Tissue Matrix ("Artia").

51. Artia was approved by the U.S. Food and Drug Administration ("FDA") on February 24, 2017. Artia 510(k) Premarket Notification (attached as Exhibit H) at 1. The FDA has classified Artia as a collagen mesh. *Id.* at 3.

52. The U.S. National Library of Medicine's Global Unique Device Identification Database (GUDID) lists Artia as "[a] sterile, bioabsorbable, flat or three-dimensional (3-D) implantable material made from animal-derived collagen intended for multiple tissue defect repair/hernia reduction (e.g., inguinal, ventral/incisional, umbilical, femoral) applications including an extra-abdominal application(s) [e.g., plastic surgery, breast reconstruction]" that can be stored at temperatures between "-8 and 30 degrees Celsius." https://accessgudid.nlm.nih.gov/devices/M328082010970 (visited February 27, 2017) (attached as Exhibit I) at 1, 2.

53. Defendant makes the following claims about Artia:

- "ARTIA™ Acellular Dermal Matrix (new porcine based ADM)," is identified as a "Key" product in the "Plastic Reconstruction Surgery" market. Investor slides entitled "Allergan to Acquire Acelity L.P.'s LifeCell Corporation for $2.9 Billion" (attached as Exhibit J) at 5.
- Artia Reconstructive Tissue Matrix is "a new porcine acellular dermal matrix" introduced in the U.S. and Europe. Acelity Press Release (attached as Exhibit K) at 1.
- "LifeCell has also developed ARTIA™, a porcine based tissue matrix . . . ." Allergan Press Release (attached as Exhibit L) at 1.
- "In addition to its commercial products, upon close Allergan will also acquire LifeCell's innovative manufacturing capabilities and its R&D operations, based in New Jersey." *Id.*

54. Upon information and belief, Artia is a plasticized soft tissue graft as set forth in at least claims 1-4, 17, 18, 20, and 36 of the '420 patent.

55. Upon information and belief, Artia is a plasticized soft tissue graft produced by the methods set forth in at least claims 8, 23, 24, 26, 29, and 32 of the '420 patent.

56. Upon information and belief, Defendant has been using, manufacturing, selling, and offering for sale a tissue product under the brand name AlloDerm Regenerative Tissue Matrix Ready to Use ("AlloDerm RTU").

57. Defendant makes the following claims about AlloDerm RTU:

- AlloDerm RTU is "allograft human dermis, processed to remove cells while preserving biologic components and structure of the dermal matrix." AlloDerm RTU Instructions for Use (attached as Exhibit M) at 2;
- AlloDerm RTU storage is "at room temperature in its original packaging." *Id.* at 3;
- "AlloDerm® RTM *Ready to Use* storage is at room temperature (8-30C /18-86F)." AlloDerm Frequently Asked Questions Page (attached as Exhibit N) at 1; and
- AlloDerm RTU is "ready to use with a minimum 2-minute soak and sterile" and "saves substantial operating time by eliminating the rehydration step." AlloDerm RTU Brochure (attached as Exhibit O) at 2.

58. AlloDerm RTU was found to infringe claims 1-4, 7, 8, and 10 of the '200 patent. See '200 patent litigation, D.I. 369 at 4.

59. Upon information and belief, AlloDerm RTU is a plasticized soft tissue graft as set forth in at least claims 1-4, 17, 18, 20, 21, and 36 of the '420 patent.

60. Upon information and belief, AlloDerm RTU is a plasticized soft tissue graft produced by the methods set forth in at least claims 8, 23, 24, 26, 27, 29, and 32 of the '420 patent.

61. Upon information and belief, Defendant has been using, manufacturing, selling, and offering for sale a tissue product under the brand name AlloDerm Select Regenerative Tissue Matrix Ready to Use ("AlloDerm Select").

62. Defendant makes the following claims about AlloDerm Select:

- AlloDerm Select is "donated allograft human dermis, processed to remove cells while preserving biologic components and structure of the dermal

matrix." http://www.acelity.com/products/alloderm-select (visited February 23, 2017) (attached as Exhibit P) at 19.

- "Store product at room temperature in its original packaging." AlloDerm Select Regenerative Tissue Matrix Ready to Use Instructions for Use (attached as Exhibit Q) at 4.

63. Upon information and belief, AlloDerm Select is a plasticized soft tissue graft as set forth in at least claims 1-4, 17, 18, 20, 21, and 36 of the '420 patent.

64. Upon information and belief, AlloDerm Select is a plasticized soft tissue graft produced by the methods set forth in at least claims 8, 23, 24, 26, 27, 29, and 32 of the '420 patent.

65. Defendant has sold and offered for sale, and continues to sell and offer for sale Strattice, Strattice Extra Thick, Strattice Laparoscopic, Strattice Perforated, Conexa, AlloDerm RTU, and AlloDerm Select in this Commonwealth and this District, including but not limited to hospitals and other surgical centers.

D. LifeCell's Infringement of the '420 Patent Is Willful as It Has Long Known That the Patent Claims Cover Its Infringing Products

66. LifeCell has long been aware of LifeNet Health's Preservon® technology. As stated above in paragraphs 23 and 24, LifeNet Health filed suit against LifeCell for infringement of the '200 patent in 2013. And, in fact, LifeCell has been aware of LifeNet Health's Preservon® technology for far longer—since at least 2009. *See* '200 patent litigation, D.I. 1 at ¶¶ 31-40.

67. With respect to the '420 patent in particular, LifeCell has known about the '634 application (which is the application that led to the '420 patent) since at least March 10, 2014. On that date—which was during discovery in the '200 patent litigation—then-counsel for LifeCell wrote to counsel for LifeNet Health about the application. Letter from Gary M. Rubman, counsel for LifeCell, Covington & Burling LLP, to Michael H. Jacobs and Warren A.

Zitlau, counsel for LifeNet Health, Crowell & Moring LLP and Cahn & Samuels LLP, respectively (March 10, 2014) (attached as Exhibit R).

68. Further, during discovery in the ’200 patent litigation, LifeNet Health explicitly put LifeCell on notice of the ’634 application by including infringement allegations directed to the then-allowed claims of that application. LifeNet Health’s Preliminary Response to LifeCell’s First Set of Interrogatories (1-18), served on counsel for LifeCell on April 18, 2014, Response to Interrogatory No. 2, at 6-8 (attached as Exhibit S); *see also* Exhibits C and D to LifeNet Health’s Response to Interrogatory No. 2 (as these exhibits exceed 500 total pages, excerpts of these exhibits are submitted herewith as Exhibits T and U, respectively).

69. The facts concerning LifeCell’s willfulness, however, go far beyond its counsel’s letter regarding the prosecution of the ’420 patent and LifeNet Health’s infringement allegations during the ’200 patent litigation.

70. During the ’200 patent litigation, LifeCell repeatedly raised issues concerning pending applications in the ’970 patent family, including the ’634 application. *See*, *e.g.*, ’200 patent ligation, D.I. 47 (Memorandum in Support of LifeCell’s Motion to Compel Full and Complete Discovery Responses) at 5 (“LifeNet continues to seek from the Patent Office additional patents that claim priority back to the 1998 application.”), and 15 n.3 (“LifeNet also continues to prosecute patent applications that are in the same family as the ’200 patent and involve similar subject matters [sic] . . . .”); D.I. 68 (Rebuttal Brief in Support of LifeCell’s Motion to Compel Full and Complete Discovery Responses) at 6 (“LifeNet has prosecuted twelve different patent applications to date that claim direct priority to the same application as the ’200 patent, and continues to prosecute four such applications.”). LifeCell further

acknowledged that the ’634 application shares the same specification as the ’200 patent. D.I. 62 (Defendant LifeCell Corp.’s Opening Claim Construction Brief) at 10-11.

71. Further, LifeCell pointed to the claims and the file history of the ’634 application during the claim construction phase of the ’200 patent litigation, acknowledging that the independent claims of the ’634 application were directed to a “plasticized soft tissue graft.” *Id.* at 11 n.2 (quoting application claims 17, 18, and 19). LifeCell was also aware that the ’634 application had a dependent claim where the plasticized soft tissue graft “comprise[s] collagen fibers . . . and the native orientation of the collagen fibers is maintained in said plasticized soft tissue graft,” which is recited in independent claim 1 in the ’420 patent. *See id.* at 11. In fact, claim 1 of the ’420 patent includes all of the elements of application claim 17, as quoted in LifeCell’s claim construction brief, plus the subject matter of application claim 46—also discussed in the brief—directed to maintaining the native orientation of the collagen fibers.

72. Claim 1 of the ’420 patent recites:

> A plasticized soft tissue graft suitable for transplantation into a human, comprising:
>
> a cleaned soft tissue graft having an internal matrix; and
>
> one or more plasticizers contained in said internal matrix,
>
> wherein said cleaned soft tissue graft comprise collagen fibers and the native orientation of the collagen fibers is maintained in said plasticized soft tissue graft.

73. LifeCell has long been aware that each of its Infringing Products meets every element of multiple claims in the ’420 patent and, therefore, that these products would infringe upon issuance of the patent. The infringement of claim 1 by Strattice and AlloDerm RTU is specifically addressed below by way of example.

74. Upon information and belief, Strattice Extra Thick, Strattice Laparoscopic, Strattice Perforated, Conexa, and Artia infringe the ’420 patent, including claim 1, for at least the same reasons as Strattice.

75. Upon information and belief, AlloDerm Select infringes the ’420 patent, including claim 1, for at least the same reasons as AlloDerm RTU.

1. LifeCell’s Infringement of the ’420 Patent by Strattice

a. Strattice Is “a Plasticized Soft Tissue Graft Suitable for Transplantation into a Human”

76. Strattice is a plasticized soft tissue graft suitable for transplantation into a human. ’200 patent litigation, D.I. 188 (Declaration of David L. Kaplan, Ph.D. in Support of LifeNet Health’s Motion for Summary Judgment) at 13. In the ’200 patent litigation, LifeNet Health’s technical expert, Dr. David Kaplan, explained that LifeCell itself described Strattice as “an acellular reconstructive tissue matrix . . . derived from porcine dermis, which undergoes nondamaging proprietary processing that removes cells and significantly reduces the key component believed to play a major role in the xenogeneic rejection response.” *Id*.

77. Additionally, Dr. Kaplan explained that LifeCell described Strattice as “a surgical mesh that is derived from porcine skin that is processed and preserved in a phosphate buffered aqueous solution containing matrix stabilizers.” *Id.* at 13-14 (citing LifeCell’s LTM-BPS 510(k) Pre-market Notification at 41, 53); *see also* LifeCell 510(k): LRTM Surgical Mesh IFU at 41, 54; Charles Bellows *et al*., Early report of a randomized comparative clinical trial of Strattice™ reconstructive tissue matrix to lightweight synthetic mesh in the repair of inguinal hernias, 18 HERNIA 221 (2014)) at 222; LifeCell Strattice Reconstructive Tissue Matrix Instructions for Use (Europe) at 3. The Strattice Instructions for Use indicates that the intended use is transplantation

into a human. D.I. 188 at 18, 19; LifeCell 510(k): LRTM Surgical Mesh IFU at 41, 54; and Bellows at 222.

b. Strattice Is "a Cleaned Soft Tissue Graft Having an Internal Matrix"

78. Strattice is a cleaned soft tissue graft having an internal matrix. '200 patent litigation, D.I. 188 at 24 (citing Strattice Product Web Page (http://www.lifecell.com/health-careprofessionals/lifecell-products/stratticetm-reconstructive-tissue-matrix) at 1 (Strattice is "an acellular reconstructive tissue matrix . . . derived from porcine dermis, which undergoes non-damaging proprietary processing that removes cells and significantly reduces the key component believed to play a major role in the xenogeneic rejection response.")). Strattice has an internal matrix that "behaves like a natural scaffold for tissue remodeling by the host until it is completely substituted by the host's mature and newly formed tissue, theoretically making it more physiologic than synthetic prostheses." *Id.* at 25 (citing Bellows at 222).

c. Strattice Has "One or More Plasticizers Contained in [Its] Internal Matrix"

79. The evidence presented in the '200 patent litigation demonstrates that in the accused products, the free and loosely bound water of hydration in the tissue have been replaced with one or more plasticizers. '200 patent litigation, Redacted Trial Tr. at 461:18-465:3, 483:20-485:4. Specifically, Dr. Kaplan stated that Strattice has one or more plasticizers contained in the internal matrix. D.I. 188 at 31. Additionally, as Dr. Kaplan explained, Strattice can be stored at room temperature with conventional packaging, which would not be possible if the plasticizers were not contained in the internal matrix. D.I. 188 at 33 (citing Strattice Instructions for Use at 5).

80. Additionally, during the '200 patent litigation the evidence demonstrated that any rinse of the accused products does not remove plasticizers from the internal matrix of the graft.

'200 patent litigation, Redacted Trial Tr. at 465:4-14; 467:13-24; 495:2-14; 499:3-500:13; 503:10-21; 509:9-11; 513:25-517:1; 526:24-527:3; 527:18-23. As Dr. Kaplan explained, "if you tried to remove the plasticizer from the internal matrix, you would have to disrupt the matrix to get it back out, and that would destroy the integrity of the tissue and you'd lose the mechanical properties."). *Id*. at 503:17-21. The evidence also clearly shows LifeCell's products do not experience a loss of mechanical properties or a disruption of the collagen orientation even after a rinse, thus supporting Dr. Kaplan's testimony on the non-removal of the plasticizer from the internal matrix. *Id*. at 488:5-23; 492:2-6; 503:25-504:1; 507:23-508:22; 510:9-512:20. Dr. Kaplan explained the science behind the interactions of the matrix components and glycerol, the properties of the tissue grafts after plasticization, and what would be required to actually remove plasticizer from the internal matrix based on the underlying scientific principles. *E.g. id*. at 461:18-465:14, 467:7-469:15, 499:7-500:13, 503:10-21. Dr. Kaplan explained that, in view of the evidence that the tissue graft is composed of the internal matrix and void spaces, the "bulk water" that fills the void spaces is not part of the internal matrix, whereas the plasticizer that interacts with the matrix components, creating a shield around the matrix structure are the "plasticizers contained in said internal matrix." *Id*. at 463:14-464:1.

d. In Strattice, "the Cleaned Soft tissue Graft Comprise[s] Collagen Fibers and the Native Orientation of the Collagen Fibers Is Maintained in [the] Plasticized Soft Tissue Graft"

81. Strattice comprises collagen fibers and the native orientation of the collagen fibers is maintained in the plasticized graft. '200 patent litigation, D.I. 188 at 14-15. As Dr. Kaplan explained, LifeCell's documents confirm this to be true. Redacted Trial Tr. at 485:5-486:5, 491:25-492:23.

2. LifeCell's Infringement of the '420 Patent by AlloDerm RTU

a. AlloDerm RTU Is "a Plasticized Soft Tissue Graft Suitable for Transplantation into a Human"

82. AlloDerm RTU is a plasticized soft tissue graft suitable for transplantation into a human. '200 patent litigation, D.I. 188 at 10. Dr. Kaplan stated that, according to LifeCell's website, "AlloDerm® Tissue Matrix [is] composed of donated human dermal tissue. This donated tissue is recovered, processed, stored and distributed in conformance with the regulations of the Food and Drug Administration (FDA) and various State legislatures as well as the Standards of the American Association of Tissue Banks (AATB)." D.I. 188 at 10 (citing LifeCell website, "AlloDerm", FAQ (http://www.lifecell.com/health-careprofessionals/lifecell-products/AlloDermr-regenerative-tissue-matrix/faqs/)). The AlloDerm Instructions for Use indicate that the intended use is transplantation into a human. *Id.* at 17-18 (citing AlloDerm Regenerative Tissue Matrix Ready to Use Instructions for Use at 1).

b. AlloDerm RTU Is "a Cleaned Soft Tissue Graft Having an Internal Matrix"

83. AlloDerm is a cleaned soft tissue graft having an internal matrix. *Id.* at 11 (citing AlloDerm Regenerative Tissue Matrix Ready to Use "Now ready when you are" at 2 ("AlloDerm RTM Ready to Use preserves the structure and the integrity of the human dermal matrix.")). LifeCell asserts that "AlloDerm® Regenerative Tissue Matrix Ready To Use . . . is donated allograft human dermis, processed to remove cells while preserving biologic components and structure of the dermal matrix." *Id.* at 21 (citing AlloDerm Regenerative Tissue Matrix Ready to Use Instructions for Use at 1; and LifeCell website, "AlloDerm", FAQ (http://www.lifecell.com/healthcare-professionals/lifecell-products/AlloDermr-regenerative-tissue-matrix/faqs/) at 2 (indicating that "LifeCell tissue grafts undergo a patented process that

cleans and removes the cellular components while preserving and stabilizing the biochemical and biomechanical properties of the grafts.")).

c. AlloDerm RTU Has "One or More Plasticizers Contained in [Its] Internal Matrix"

84. The evidence presented in the '200 patent litigation demonstrates that in the accused products, the free and loosely bound water of hydration in the tissue have been replaced with one or more plasticizers. *Id.* at 31; and '200 patent litigation, Redacted Trial Tr. at 461:18-465:3, 483:20-485:4. Additionally, as Dr. Kaplan explained, AlloDerm RTU can be stored at room temperature with conventional packaging—a feat that could not be achieved if the plasticizers were not contained in the internal matrix. D.I. 188 at 31 (citing AlloDerm RTU Instructions for Use at 3).

85. Additionally, during the '200 patent litigation the evidence demonstrated that any rinse of the accused products does not remove plasticizers from the internal matrix of the graft. Redacted Trial Tr. at 465:4-14; 467:13-24; 495:2-14; 499:3-500:13; 503:10-21; 509:9-11; 513:25-517:1; 526:24-527:3; 527:18-23. As Dr. Kaplan explained, "if you tried to remove the plasticizer from the internal matrix, you would have to disrupt the matrix to get it back out, and that would destroy the integrity of the tissue and you'd lose the mechanical properties."). *Id*. at 503:17-21. The evidence also clearly shows LifeCell's products do not experience a loss of mechanical properties or a disruption of the collagen orientation even after a rinse, thus supporting Dr. Kaplan's testimony on the non-removal of the plasticizer from the internal matrix. *Id.* at 488:5-23; 492:2-6; 503:25-504:1; 507:23-508:22; 510:9-512:20. Dr. Kaplan explained the science behind the interactions of the matrix components and glycerol, the properties of the tissue grafts after plasticization, and what would be required to actually remove plasticizer from the internal matrix based on the underlying scientific principles. *See, e.g., id*. at 461:18-465:14,

467:7-469:15, 499:7-500:13, 503:10-21. Dr. Kaplan explained that, in view of the evidence that the tissue graft is composed of the internal matrix and void spaces, the "bulk water" that fills the void spaces is not part of the internal matrix, whereas the plasticizer that interacts with the matrix components, creating a shield around the matrix structure are the "plasticizers contained in said internal matrix." *Id*. at 463:14-464:1.

d. In AlloDerm RTU, "the Cleaned Soft tissue Graft Comprise[s] Collagen Fibers and the Native Orientation of the Collagen Fibers Is Maintained in [the] Plasticized Soft Tissue Graft"

86. AlloDerm comprises collagen fibers and the native orientation of the collagen fibers is maintained in the plasticized graft. '200 patent litigation, D.I. 188 at 12. LifeCell public documents confirm this to be true: "AlloDerm RTM Ready to Use preserves the structure and the integrity of the human dermal matrix. The native collagen architecture, including basement membrane structure, is maintained through gentle processing in both AlloDerm RTM and AlloDerm RTM Ready to Use." *Id.* (citing AlloDerm Regenerative Tissue Matrix Ready to Use "Now ready when you are" at 2.)

IV. COUNT I: INFRINGEMENT OF THE '420 PATENT

87. Plaintiff LifeNet Health realleges and incorporates by reference paragraphs 1 through 86 of this Complaint as though fully set forth herein.

88. Defendant LifeCell is infringing at least claims 1-4, 8, 17, 18, 20, 23, 24, 26, 29, 32, and 36 of the '420 patent by, without LifeNet Health's authority, manufacturing, causing to be manufactured, using, offering for sale, and selling in the United States at least the Infringing Xenograft Products.

89. Defendant LifeCell is infringing at least claims 1-4, 8, 17, 18, 20, 21, 23, 24, 26, 27, 29, 32, and 36 of the '420 patent by, without LifeNet Health's authority, manufacturing,

causing to be manufactured, using, offering for sale, and selling in the United States at least the Infringing Allograft Products.

90. Defendant LifeCell has been aware of the application that matured into the '420 patent since at least as early as 2014. More specifically, Defendant LifeCell has been aware that its Infringing Products are covered by multiple claims of the '420 patent since at least November 2014, when the jury in the '200 patent litigation determined that Strattice, AlloDerm RTU, and Conexa infringe the '200 patent.

91. Despite its knowledge of the '420 patent, and despite an objectively high likelihood that its actions constitute infringement, Defendant LifeCell's sale of the Infringing Products is an egregious case of misconduct far beyond that of typical infringement. LifeCell's infringement, therefore, is willful.

92. LifeNet Health has suffered monetary and other damages by reason of Defendant LifeCell's infringement of the '420 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff LifeNet Health requests relief against Defendant LifeCell Corporation as follows:

(a) A judgment that Defendant has directly infringed the '420 patent;

(b) A judgment that Defendant's infringement has been willful;

(c) A judgment and order requiring Defendant to pay damages under 35 U.S.C. § 284, including treble damages for willful infringement, together with costs and prejudgment and post-judgment interest;

(d) An order for a preliminary injunction under 35 U.S.C. § 283 requiring LifeCell to cease manufacturing, causing to be manufactured, using, offering for sale, and selling in the United States the Infringing Xenograft Products;

(e) An order for a permanent injunction under 35 U.S.C. § 283 requiring LifeCell to cease manufacturing, causing to be manufactured, using, offering for sale, and selling in the United States the Infringing Xenograft Products;

(f) A finding that this case is an exceptional case, and an order awarding Plaintiff its costs and reasonable attorney fees under 35 U.S.C. § 285; and

(g) Any and all such other and further relief as the Court may deem appropriate.

JURY DEMAND

LifeNet Health hereby demands a trial by jury on all issues triable to a jury.

Dated: February 28, 2017

Respectfully submitted,

LIFENET HEALTH

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